

DEC 23 2003

## Appendix A Summary of Safety and Effectiveness

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

### 1. Submitters Information

Contact person: Mary E. Gray, RAC  
NPT Regulatory Affairs Manager

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Subsidiary of Bayer Corporation  
63 North Street  
Medfield, MA 02052

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Date Summary Prepared: November 7, 2003

### 2. Device Information

Proprietary Name: Clinitest® hCG Pregnancy Test

Common Name: hCG Test System

Classification Name: Radioimmunoassay, Human Chorionic Gonadotropin

Classification Number: 21 CFR 862.1155, Class II

Classification Panel: Clinical Chemistry and Clinical Toxicology

### 3. Predicate Device Information

Device Name:	Clinitest hCG Pregnancy Test	Quidel QuickVue One-Step hCG Combo
Manufacturer:	Bayer Healthcare, LLC	Quidel Corporation
510(k) Number:	# K023944	# K020801

## **Appendix A**

### **Summary of Safety and Effectiveness**

#### **4. Device Description**

The Clinitest<sup>®</sup> hCG is a qualitative test for the rapid detection of human chorionic gonadotropin (hCG) in urine. The device is read by the Clinitek Status instrument.

#### **5. Statement of Intended Use**

The Bayer Healthcare Clinitest hCG Pregnancy Test is for in vitro diagnostic use as a qualitative method in the rapid detection of human chorionic gonadotropin (hCG) in urine specimens. The test is utilized with the Clinitest Status analyzer and is intended for near patient (point of care) and centralized laboratory locations.

#### **6. Summary of Technological Characteristics**

The Clinitest hCG Pregnancy Test is similar in technological characteristics, device performance and intended use, therefore, is substantially equivalent to the predicate devices, the Clinitest hCG Pregnancy Test (# **K023944**) and the Quidel QuickVue One-Step hCG Combo test (# **K020801**).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

DEC 23 2003

Ms. Mary E. Gray  
NPT Regulatory Affairs Manager  
Bayer Healthcare, LLC  
Subsidiary of Bayer Corporation  
63 North Street  
Medfield, MA 02052

Re: k032563  
Trade/Device Name: Clinitest<sup>®</sup> hCG Pregnancy Test  
Regulation Number: 21 CFR 862.1155  
Regulation Name: Human chorionic gonadotropin (HCG) test system  
Regulatory Class: Class II  
Product Code: JHI  
Dated: November 7, 2003  
Received: November 10, 2003

Dear Ms. Gray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

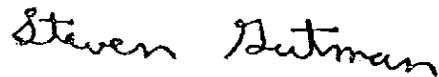
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.  
Director  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

